



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/720,909

11/24/2003

Roland Janzen

DCS-9151

5291

34500 7590 02/06/2007

DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

VENCI, DAVID J

ART UNIT

PAPER NUMBER

1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

02/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/720,909		JANZEN ET AL.	
	Examiner		Art Unit	
	David J. Venci		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 22, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 and 14-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

DETAILED ACTION

Election/Restrictions

Amended claims 7 and 12 are directed to an invention that is independent or distinct from the invention originally claimed. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 14-16, drawn to reagents comprising, *inter alia*, a fluid medium, classified in class 252/397, for example.
- II. Claims 7, 8 and 12, drawn to reagents comprising, *inter alia*, a containing, classified anywhere in class 96, for example.
- III. Claims 9-11 and 17-21, drawn to method, classified in class 436/518, for example.

Inventions I and II are related products. Related products are distinct from each other if the products, as claimed, are not: (1) capable of use together or have a materially different design, mode of operation, function, or effect; (2) overlapping in scope, i.e., are mutually exclusive; and (3) obvious variants. See MPEP § 806.05(j).

Here, Inventions I and II have different modes of operation and different functions because Invention I requires a fluid medium, while Invention II requires a containing.

The scopes of Inventions I and II do not appear to overlap because Invention I requiring a fluid medium does not appear to infringe Invention II requiring a containing. In addition, there is no indication on the record of a specific example of a single product that infringes either Inventions I or II.

Art Unit: 1641

Inventions I and II are not obvious variants because said fluid medium and said containing have different structures. Furthermore, there is no indication on the record that the Inventions would have been obvious variants over each other within the meaning of 35 U.S.C. 103(a).

Examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for the fluid medium of Invention I requires a search of prior art related to liquid things, while a search for the containing of Invention II requires a search of prior art related to solid things.

Inventions (I or II) and III are related as products and process of their use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the products as claimed can be practiced with another materially different product or (2) the products as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Invention (I or II) can be used in a materially different process, such as a process for assaying first binding species.

As indicated, *supra*, restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art.

Since applicant has received an action on the merits for the originally presented invention corresponding to Invention I, claims 1-6 and 14-16, Invention I has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 7-12 and 17-21 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Currently, claims 1-6 and 14-16 are under examination.

Specification

The disclosure is objected to for various informalities. Appropriate correction is required.

Examiner objects to the general contents of paragraphs [0035], [0040], [0041], [0043] and Tables 1-6 for reference to, and reliance upon data obtain from commercially manufactured LOCI™ TSH and FT3 assays. Applicants' specification does not clearly disclose the contents of each of said commercially manufactured assays. Applicants' specification does not clearly disclose experimental protocols for using each of said commercially manufactured assays. In Tables 1-6, the recitation of "Level" is indefinite because it is not clear what "Level" is measured or the exact quantity or unit of measurement of the various "Levels"

In paragraph [0038], first sentence, the phrases "the binding pair members" and "the solid-phase" lack antecedent bases.

Art Unit: 1641

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

The objects "an assay" and "an assay of an analyte" are indefinite. The identity of one or more components, if any, belonging to "assay" is not clear.

The phrase "dissociated first binding species" is indefinite. The identity of two or more objects subject to dissociation is not clear. Whether said "first binding species" is dissociated from "first substrate" AND/OR/NOT "a second substrate" AND/OR/NOT "binding regions" AND/OR/NOT "binding partners" is not clear.

The phrase "the signal strength" lacks antecedent basis.

The phrase "detrimentally affecting" lacks antecedent causal basis. The cause(s) of said detrimental effect is not clear.

In claim 14:

The phrase "said dissociated first binding species" lacks antecedent basis.

The phrase "the signal strength" lacks antecedent basis.

Art Unit: 1641

The phrase "said assay" lacks antecedent basis. The identity of one or more objects, if any, belonging to "assay" is not clear.

The phrase "regions capable of selectively binding" is indefinite. The mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that provide capability is/are not clear.

The duplicate recitation of the term "regions" is indefinite. Whether the space occupied by the first recitation of the term "region" is coextensive with the space occupied by one or more "second regions" is not clear. The degree of coextensive spatial overlap, if any, is not clear.¹

The phrase "detrimentally affecting" lacks antecedent causal basis. The cause(s) of said detrimental effect is not clear.

¹ Applicants may obviate this rejection by reciting ordinal descriptors to describe "regions" (e.g., first region, second region).

Art Unit: 1641

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman *et al.* (US 6,406,913).

Ullman *et al.* teach a reagent comprising:

a fluid medium (see col. 36, lines 1-32) containing:

- a. a first substrate (see col. 19, lines 47-65) having a first binding species (see col. 14, lines 55-67) attached thereto (see col. 19, lines 66-67), said first binding species capable of dissociating from the first substrate (see col. 20, line 8, "non-covalent interactions"); and
- b. a second substrate having binding regions having binding partners capable of selectively binding said first binding species (see col. 35, lines 36-38, see col. 37, lines 28-35).

The language "without detrimentally affecting the signal strength of said assay" does not structurally differentiate Applicants' invention from the reagent of Ullman *et al.* because Examiner considers such language as functional in nature. According to MPEP 2114, a claim containing a recitation with respect to

Art Unit: 1641

the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim.

With respect to claims 2-3 and 15-16, Ullman *et al.* teach a reagent wherein the first substrate and second substrates are the same material or different material (see col. 21, lines 23-35).

With respect to claim 14, Ullman *et al.* teach a reagent wherein specific binding pair members are located on the surface (see col. 14, lines 55-56) of different supports (see col. 19, lines 47-65) and are used in a competitive assay format (see col. 35, lines 36-38, see col. 37, lines 28-35) wherein one binding member is complementary to the other binding member (see col. 37, lines 28-35).

Art Unit: 1641

Response to Arguments

Specification

In prior Office Action, Examiner objected to the disclosure for various informalities. Specifically, Examiner objects to the general contents of paragraphs [0035], [0040], [0041], [0043] and Tables 1-6 for reference to, and reliance upon data obtain from commercially manufactured LOCI™ TSH and FT3 assays. Applicants' specification does not clearly disclose the contents of each of said commercially manufactured assays. Applicants' specification does not clearly disclose experimental protocols for using each of said commercially manufactured assays. In Tables 1-6, the recitation of "Level" is indefinite because it is not clear what "Level" is measured or the exact quantity or unit of measurement of the various "Levels".

In response, Applicants argue, in part², that "the type of units that [level] is measured in is not critical to the invention" (see Applicants' reply, p. 9, last paragraph, third sentence) (paraphrasing mine).

Applicants' argument has been carefully considered but is not persuasive.

According to M.P.E.P. 2161, the requirements of 35 U.S.C. 112, first paragraph, are not merely limited to claimed subject matter, but are applicable to Applicant's entire specification. Thus, Examiner posits that the aforementioned objection to the specification is maintainable insofar as Applicants' entire specification does not enable one skilled in the art to make Applicant's claimed reagent satisfying a certain "level" of utility.

Claim Rejections - 35 USC § 112

In prior Office Action, claims 1 and 14 were rejected under 35 U.S.C. 112, second paragraph, because the phrase "the signal strength" lacks antecedent basis.

Art Unit: 1641

In response, Applicants argue that a "signal" and "signal strength" are inherent in the term "assay", thus obviating the need for antecedent basis.

Applicants' argument has been carefully considered but is not persuasive.

Insofar as the claimed "assay" is an inanimate object³, Examiner posits that the claimed "assay" is incapable of possessing or inheriting "signal" or "signal strength".

In prior Office Action, claim 14 was rejected under 35 U.S.C. 112, second paragraph, because the phrase "regions capable of selectively binding" was considered indefinite. The mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that provide capability is/are not clear.

In response, Applicants allude to a substrate coupled with "a material" (see Applicants' reply, p. 11, first full paragraph, third sentence, "The scavenger substrate may be coupled with *a material* that binds the dissociated binding species[...]") (paraphrasing and emphasis mine).

Applicants' argument has been carefully considered but is not persuasive. Persons of ordinary skill may not be so imaginative as to imagine the existence of "a material" in claim 14, or import the clarifying details from Applicants' argumentation into the plain meaning of claim 14, to arrive at Applicants' invention as described in Applicants' argumentation.

² Please note, Examiner does not question whether persons of ordinary skill have general knowledge of how to perform assays, make calibration curves, or whether a government website uses the terms "level" and TSH in the same sentence.

³ See *supra*, Claim Rejections - 35 USC § 112. The objects "an assay" and "an assay of an analyte" are considered indefinite.

Art Unit: 1641

Claim Rejections - 35 USC § 102

In prior Office Action, claims 1-6 and 14-16 were rejected under 35 U.S.C. 102(b) as being anticipated by Ullman *et al.* (US 6,406,913).

In response, Applicants provide argumentation that appears premised on assertions that Ullman *et al.* do not teach:

- (1) "dissociated" first binding species (*i.e.*, first binding species not attached to substrate);
- (2) partners capable of binding "dissociated" first binding species (*i.e.*, partners capable of binding first binding species not attached to substrate)

Applicants' argument has been carefully considered but is not persuasive.

With respect to 1), see Lodish *et al.*, MOLECULAR CELL BIOLOGY, W.H. Freeman & Co. (2000), who teach the art-recognized inherency of "dissociated" binding species, especially non-covalent binding species.

With respect to 2), Ullman *et al.* teach a second substrate having binding regions having binding partners capable of selectively binding said first binding species (see col. 35, lines 36-38, see col. 37, lines 28-35). According to MPEP 2114, a claim containing a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim.

Art Unit: 1641

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv



LONG V. LE 02/01/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600